510(k) SUMMARY— Apaceram™ Bone Void Filler

Submitter Name:	Pentax Corporation
Submitter Address:	2-36-9 Maeno-cho Itabashi-ku, Todyo 174-8639 JAPAN
Contact Person:	Hiroyasu Takeuchi Vice President, General Manager New Ceramics Division
Phone Number:	813-3960-1290
Fax Number:	813-3960-2681
Date Prepared:	July 11, 2007
Device Trade Name:	Apaceram™ Bone Graft Substitute
Device Common Name:	Synthetic, porous hydroxylapatite
Classification Number:	21 CFR 888.3045
Classification Name:	Resorbable calcium salt bone void filler
Product Code:	MQV
Predicate Devices:	K033722, ApaPore® Bone Graft Substitute, ApaTech Ltd. K051774, MBCP™, Biomatlante.
Statement of Intended Use:	Apaceram™ Bone Graft Substitute is a synthetic hydroxyapatite provided in several particulate and shaped sizes. It is intended for use as a bone void filler for bony voids, gaps, or defects that are not intrinsic to the stability of the bony structure. Apaceram™ is intended to be placed into bony voids or gaps of the skeletal system (i.e. extremities, spine, or pelvis) caused by degeneration, trauma or surgery. It also can be used with autograft as a bone graft extender. Apaceram™ is resorbed and replaced with bone during the healing process.
Device Description:	Apaceram™ is a hydroxyapatite osteoconductive bone void filler. It is available in four types: AX, B, G, and R, which vary in porosity, shape and sizes. Apaceram™ is provided sterile for single patient use.
Technological Characteristics and Substantial Equivalence:	The Apaceram™ and the predicate devices are similar in design, material composition, final product configurations, and function. They are made of calcium salts, are osteoconductive, and provide an interconnected, highly porous scaffold environment for new bone ingrowth. The safety and biocompatibility testing performed by Pentax and a long history of safe clinical use of this material support the safety and effectiveness of Apaceram™ and its equivalence to the predicate devices.

OCT 29 2007

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 29 2007

Pentax Corp.
% Patsy J. Trisler, J.D., RAC
Regulatory Consultant
5600 Wisconsin Avenue
Suite 509
Chevy Chase, Maryland 20815

Re: K071912
Trade/Device Name: Apaceram™ Bone Graft Substitute
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: July 11, 2007
Received: July 11, 2007

Dear Ms. Trisler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

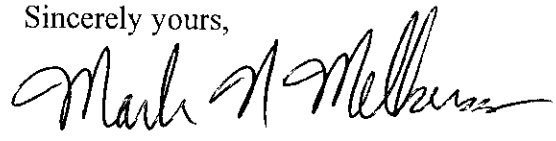
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Apaceram™ Bone Graft Substitute

Indications for Use:

Apaceram™ Bone Graft Substitute is a synthetic hydroxyapatite provided in several particulate and shaped sizes. It is intended for use as a bone void filler for bony voids, gaps, or defects that are not intrinsic to the stability of the bony structure. Apaceram™ is intended to be placed into bony voids or gaps of the skeletal system (i.e. extremities, spine, or pelvis) caused by degeneration, trauma or surgery. It also can be used with autograft as a bone graft extender. Apaceram™ is resorbed and replaced with bone during the healing process.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071912